

REMARKS

I. Amendments and Status of the Claims

Claims 1, 2, and 7-27 are pending, with claims 1 and 27 being independent.

Claims 1, 7, 8, and 15 have been amended, without prejudice to pursue any canceled subject matter in a continuing application, and without disclaimer of any subject matter.

Claim 1 has been amended to recite "at least one subsequent production batch." A subsequent production batch finds support in the definition of the preproduction batch, and by the disclosure of the subsequent preproduction batch. See specification at 2, lines 30-32. Claim 1 also now recites "wherein the cells of the at least one production batch of c) have a different passage number than the cells of the at least one subsequent production batch." Support for those production batches having different passage numbers can be found in the specification, among other places, at page 4, lines 9-13 and 26-33. For example, "Once such ECB is fully characterized one may allow to produce the product with cells at any passage number between MCB and ECB, since it may be assumed that cells have not changed in between in their specs." *Id.* at ll. 29-32. Also, the specification specifically describes production batches having different passage number X or X+1. See *id.* at ll. 9-13. Finally, claim 1 now recites language to illuminate the optional repeating step. Support for these amendments can be found throughout the application and claims as originally filed.

Claims 7 and 8 have been amended to delete an extra word.

Claim 15 has been amended to delete a trademarked term.

Claim 27 has been added to particularly point out and distinctly claim an embodiment of Applicant's invention. Support for new claim 27 can be found, among other places, in the specification at page 4, line 19 to page 5, line 3.

II. Claim Rejections over Alleged Prior Art

A. Alleged Obviousness

Claims 1, 2, and 7-26 have been rejected as allegedly obvious over *Griffiths et al.* (BRYAN GRIFFITHS & DENIS LOOBY, *Scale-Up of Suspension and Anchorage-Dependent Animal Cells*, in 75 METHODS IN MOLECULAR BIOLOGY: BASIC CELL CULTURE PROTOCOLS 59 (Jeffrey W. Pollard & John M. Walker eds., 2d ed. 1997)) and *Pollard* (JEFFREY W. POLLARD, *Basic Cell Culture*, in 75 METHODS IN MOLECULAR BIOLOGY: BASIC CELL CULTURE PROTOCOLS 1 (Jeffrey W. Pollard & John M. Walker eds., 2d ed. 1997)). Office Action at 2. Applicant respectfully disagrees with this rejection.

Without acquiescing to the rejection, or to the allegation that either *Griffiths et al.* or *Pollard* are prior art, Applicant has amended independent claim 1. Claim 1 now recites that "the cells of the at least one production batch of c) have a different passage number than the cells of the at least one subsequent production batch of f)." Neither *Griffiths et al.* nor *Pollard* teach or suggest that a biological may be produced from production batches made according to the claimed invention in which those production batches have different passage numbers. On the contrary, conventional practice shows the production of biologicals to occur in production batches all having the same passage number. See, e.g., *Wiktor et al.*, U.S. Pat. No. 4,664,912, at col. 2, ll. 68-69 (three

copies of *Wiktor et al.* accompanied Applicant's Appeal Brief); see also Applicant's specification at 1, ll. 15-20; and at 4, ll. 26-34.

"To establish a *prima facie* case of obviousness, . . . the prior art reference (or references when combined) must teach or suggest all the claim limitations." M.P.E.P. § 2143. Because the alleged prior art references do not teach or suggest the "different passage number" aspect of Applicant's claimed invention, no *prima facie* case of obviousness can be made based on *Griffiths et al.* and *Pollard*. Accordingly, Applicant respectfully requests that this obviousness rejection be withdrawn.

B. Alleged Anticipation

Claims 1, 2, 7-22, and 26 have been rejected as allegedly anticipated by *Griffiths et al.* Office Action at 5. Claims 1, 2, 10, 16-18, 22, and 25-26 also have been rejected as allegedly anticipated by *Pollard*. Office Action at 6. Applicant respectfully disagrees with these rejections.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." M.P.E.P. § 2131 (quoting *Verdegaal Bros. V. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987)). As set forth above for the non-obviousness explanation, neither *Griffiths et al.* nor *Pollard* describe the "different passage number" aspect of the claimed invention. Accordingly, Applicant respectfully requests that these anticipation rejections be withdrawn.

III. Claim Rejection under 35 U.S.C. § 112

Claim 15 has been rejected under 35 U.S.C. § 112, ¶ 2, as allegedly being indefinite for reciting an alleged trademark/trade name. Office Action at 5. In response, Applicant has deleted "Cytodex-3" from claim 15. Accordingly, this rejection should be withdrawn.

CONCLUSION

In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration and reexamination of this application and the timely allowance of the pending claims.

A Petition for Extension of Time (One Month) and fee therefor accompanies this Amendment. Please grant any further extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

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By: 

Jeremy M. Stipkala
Reg. No. 44,359